HDRN Canada
Pragmatic Trials Training Program

ICES Research Forum 2023 (May 11, 2023)

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Disclosure: I have no conflicts of interest
• What is HDRN Canada?

• What is the Pragmatic Trials Training Program?
  ▪ Objectives of the program
  ▪ Trainee streams, competencies, teaching modalities

• Joint Q&A: Amit, Scott, Kristin, Taylor
• **HDRN Canada**: pan-Canadian network

• Working together to help researchers complete multi-jurisdictional studies using routinely collected health data

[www.hdrn.ca/en/about/resources](http://www.hdrn.ca/en/about/resources)
• CIHR’s Clinical Trials Fund: May 2022

(1) Pan-Canadian trials consortium

(2) Training platforms

(3) Clinical trials

Background

The 2021 Federal Budget announced funding for CIHR’s Clinical Trials Fund (CTF), an integral component of Canada’s Biomanufacturing and Life Sciences Strategy (BLSS). In support of this, the CTF will provide funding through three specific vehicles: platforms with the development of a pan-Canadian Clinical Trials Consortium; people with the funding of training platforms; and, projects through the funding of a broad spectrum of clinical trial initiatives.

https://www.researchnet-recherchenet.ca/mr16/wwOpprntyDtls.do?all=1&masterList=true&next=1&org=CIHR&prog=3697&resultCount=25&sort=program&type=EXACT&view=currentOpps&language=E
Government of Canada announces new clinical trials consortium, training platforms, and research projects to improve the health of Canadians

From: Canadian Institutes of Health Research

News release
January 19, 2023—Hamilton, Ontario—Canadian Institutes of Health Research

Reinforcing Canada’s clinical trials infrastructure, training, and research

From: Canadian Institutes of Health Research

Backgrounder
Clinical trials are an essential part of the healthcare sector and a crucial component of medical research and innovation. Clinical trials allow researchers to assess if new drugs, treatments, and therapies are safe and effective for the population. Announced in Spring 2022, the Clinical Trials Fund earmarked $250M across three funding streams to grow and strengthen Canada’s clinical trials infrastructure, training, and research through 2025.

The CTF was launched in spring 2022 and successful applications were funded through three CTF funding streams:

- Pan-Canadian Clinical Trials Consortium: The Accelerating Clinical Trials Consortium will bring together a team of 232 researchers across the country to support and expand clinical trials networks to improve collaboration, efficiency, knowledge sharing, and quality of clinical trials in Canada.

- Clinical Trials Training Platforms: Seven different training platforms will train the next generation of clinical scientists and researchers to conduct high quality clinical trials

- Clinical Trials Projects: Twenty-two individual clinical trials projects will create the evidence needed to develop new drugs and treatments
**Clinical Trials Fund:**
- (1) Pan-Canadian trials consortium,
- (2) **Training platforms**,
- (3) Clinical trials

<table>
<thead>
<tr>
<th>Clinical Trials Training Platforms</th>
<th>Principal Investigator</th>
<th>Funding Amount</th>
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<tr>
<td>The Canadian Behavioural Trials and Interventions Training Platform</td>
<td>Dr. Simon Bacon (Concordia University)</td>
<td>$1,776,068</td>
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<tr>
<td>Canadian Consortium of Clinical Trial Training (CANTRAIN) platform: enhancing career preparedness in RCT research targeting different audiences across the continuum</td>
<td>Dr. Jean Bourbeau (Research Institute of the McGill U Health Centre)</td>
<td>$11,317,324</td>
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<tr>
<td>Canadian Training Platform for Trials Leveraging Existing Networks (CANTAP-TALENT)</td>
<td>Dr. Angela Cheung (University Health Network)</td>
<td>$4,314,242</td>
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<tr>
<td>STROKECOG Platform: Innovative Clinical Trials Training Initiatives for STROKE and COGnition</td>
<td>Dr. Jodi D. Edwards (University of Ottawa Heart Institute)</td>
<td>$2,911,416</td>
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<tr>
<td>A Training Platform in Pragmatic Registry-Based Trials: Connecting Canada’s Health, Data, and Biomanufacturing Sectors</td>
<td>Dr. Amit Garg (University of Western Ontario)</td>
<td>$3,479,320</td>
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<tr>
<td>Increasing capacity for Maternal and PAediatric Clinical Trials (IMPACT) in Canada</td>
<td>Dr. Lauren Kelly (University of Manitoba)</td>
<td>$4,907,350</td>
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<tr>
<td>Canadian Network for Statistical Training in Trials (CANSTAT)</td>
<td>Dr. Sameer Parpia (McMaster University)</td>
<td>$2,542,144</td>
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</table>

Nominated Principal Applicant:

Dr. Amit Garg
Contributors

Project title:
A Training Platform in Pragmatic Registry-Based Trials: Connecting Canada’s Health, Data, and Biomanufacturing Sectors

Principal investigator(s):
Garg, Amit; Basile, Erika; Bhatia, Rajan S; Clemens, Kristin K; Dixon, Stephanie N; Ethier, Jean-Francois; Fowler, Robert A; Gagnier, Joel J; Garrison, Scott R; Grimshaw, Jeremy M; Hohl, Corinne M; Ivers, Noah M; Jairath, Vipul; James, Matthew T; Jerath, Angela; Katz, Alan; Krzyzanowska, Monika K; Leblanc, Annie; Lee, Douglas S; Mcalister, Finlay A; McGrail, Kimberly M; McIntyre, Lauralyn A; Mittmann, Nicole; Naylor, Kyla; Pesseau, Justin; Schull, Michael J; Sontrop, Jessica M; Spence, Jessica; Swartz, Richard; Taljaard, Monica; Tangri, Navdeep; Udell, Jacob A; Weijer, Charles E; Zwarenstein, Merrick F

Co-investigator(s):
Barrett, Brendan J; Cohen, Eyal; Cowan, Andrea; Devereaux, Philip J; Fergusson, Dean A; Freier, Amy J; Gershon, Andrea S; Gill, Peter J; Golchi, Shirin; Goldstein, Cory E; Greiver, Michelle; Hebert, Paul C; Hemming, Karla; Hill, Michael D; Kimmelman, Jonathan; Kraut, Roni; Kurdyak, Paul A; Lamontagne, Francois; Lazo-Langner, Alejandro; Li, Fan; Liu, Kuan; Marlin, Susan; Menon, Bijoy K; Moe, Jessica; Ouyang, Yongdong; Parpia, Sameer; Richer, Lawrence P; Roshanov, Pavel; Sajobi, Tolulope T; Sarma, Sisira K; Schorr, Melissa; Street, Catherine A; Tennankore, Karthik K; Thabane, Lehana; Tricco, Andrea C; Wald, Ron; Winquist, Brandace D; Yada, Nicole; Young, Ann

Assigned peer review committee:
N/A

Many co-applicants & collaborators not listed here
**Pragmatic trials**: combine clinical trial design elements (i.e., randomization) & routinely collected health data

**HDRN Canada Pragmatic Trials Training Program**

- Pan-Canadian CIHR-funded training program
- Embedded within HDRN Canada
- Coordinated by Schulich School of Medicine & Dentistry, Western University (London, ON)

A new training program, coordinated by the Schulich School of Medicine & Dentistry at Western University, will help researchers use real world data in trials to generate real world evidence and improve health care services and policy.

The HDRN Canada Pragmatic Trials Training Program will launch this year, with $3.4 million in funding from the Canadian Institutes for Health Research. Led by Dr. Amit Garg, associate Dean of Clinical Research at a world-renowned clinician-scientist with the Schulich School of Medicine & Dentistry, the program will coach researchers through the complex process of conducting pragmatic trials.

"Clinical trials advance medical care, reduce the costs and burdens of illness on society, and improve health and quality of life for patients with a broad range of health conditions," said Garg, a professor of Medicine, Epidemiology and Biostatistics at Schulich Medicine and a nephrologist at London Health Sciences Centre. But barriers to these kinds of trials exist, he continued, "especially when they want to use real-world, routinely-collected data as part of them."

Pragmatic trials are designed to improve practice and policy and unlike most traditional randomized clinical trials, they take place in everyday health care settings, such as community clinics. Embedded within routine health care, pragmatic trials are analyzed using existing real-world data sources and often include patients typically excluded from traditional trials. Pragmatic trials are important because they lead to findings that accurately reflect the impact of simple interventions, which enables health care providers and organizations to gain practical evidence that they can leverage to improve health outcomes.

"Done well, pragmatic trials are faster than traditional trials and can be conducted at a fraction of the cost. Yet few Canadian researchers have the training and experience to conduct them," explained Garg. "The HDRN Canada Pragmatic Trials Training Program will allow us to mobilize Canada’s tremendous unrealized resources and provide learners with the skills needed to conduct high-quality pragmatic trials, helping a new generation conduct better, faster, cheaper and more efficient clinical trials."

Kim McIvor, Scientific Director and CEO of HDRN Canada, said the new program will help train researchers to more effectively harness health data. "We are very excited to offer this training program through HDRN Canada under Dr. Garg’s leadership," she said. "The use of real world, routinely-collected data for trials has the potential to provide timely and important evidence for health care system improvement." Dr. McIvor added that the program's focus on principles of inclusion, diversity, equity and accessibility will help ensure that pragmatic trials reflect and therefore benefit all people in Canada.

To learn more about the training and clinical trial supports that can be provided through the HDRN Canada Pragmatic Trials Training Program, sign up for our newsletter and get the latest updates.


HDRN Canada Pragmatic Trials Training Program focuses on real world data to improve health systems

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• Pragmatic Trials Training Program:

https://www.hdrn.ca

HDRN Canada
Training Platform in Pragmatic Trials Team

- Clinical
- Administrative health data
- Pragmatic registry trials
- Implementation: science and knowledge translation
- Ethics
- Methods and biostatistics

Coordinating Centre

https://www.schulich.uwo.ca/research/clinical_research/accelerating_randomized_trials.html

Schulich Medicine & Dentistry Research Office

https://www.schulich.uwo.ca

https://www.act-aec.ca

T. McLinden
Objectives:

1. Develop & deliver a pan-Canadian **training program** on conducting **pragmatic clinical trials** that are embedded in routine care & use existing data sources

   - **Existing routinely collected health data:** e.g., administrative health data, clinical registries, electronic medical records (EMR) → **in multiple jurisdictions**

2. Support the goals of CIHR’s Clinical Trials Fund by **partnering** with the Accelerating Clinical Trials (ACT) Canada Consortium & other trials training programs

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**CIHR IRSC**

https://cihr-irsc.gc.ca/e/52987.html

**ACT AEC**

https://www.act-aec.ca

**CANTRAIN**

https://wecantrain.ca
• **1. Trial leaders**
  - Faculty mentors focused on developing a pragmatic trial protocol
  - Modeled after ICES Faculty Scholars Program
    - $: Funding for protocol development support

• **2. Postdoctoral fellows**
  - Trainees paired with faculty mentors
  - Contributions to the program as educators as well
    - $: Partial salary support for 2 years

• **3. Highly qualified personnel (HQP)**
  - Public & private sector personnel wanting to upskill in pragmatic trials domain
    - $: Funding for release time for public sector HQP
Competencies

- **IDEA, Indigenous rights & data sovereignty:** dedicated full-time staff (e.g., Cultural Competency Training Coordinator), partnerships with other pan-Canadian organizations with concentrated expertise

- **Ethics:** e.g., altered patient consent for interventions being tested within routine care

- **Engagement:** e.g., patient partners, healthcare workers (particularly important for trials embedded in routine care)

- **Data sources, quality, & linkage:** e.g., complexities of administrative health data & multi-jurisdictional analyses

- **Design, methods, biostatistics:** e.g., cluster randomization, power & sample size calculations, stepped wedge designs
Teaching Modalities

- Graduate program courses on trials
- Continuing studies program(s)
- Other CIHR-funded training programs and their trainees
- HDRN Canada member organizations and associated citizen panels
- International training platforms in pragmatic clinical trials
- Prominent clinical trial units
- National clinical trial networks
- Provincial clinical trial research ethics organizations
- N2 Network of Networks
- Public health and health technology assessment government agencies
- The Indigenous Peoples’ Engagement and Research Council (IPERC)
- Private sector companies (industry and health tech incubators)

https://wecantrain.ca
• How can I learn more & stay up-to-date?

  ▪ **Web:** Google “HDRN pragmatic” & “Western pragmatic”
    - [www.schulich.uwo.ca/research/student_trainee_programs/pragmatic_trials_training_program.html](http://www.schulich.uwo.ca/research/student_trainee_programs/pragmatic_trials_training_program.html)

  ▪ **Social media:**
    - [www.twitter.com/HDRN_RRDS](http://www.twitter.com/HDRN_RRDS) & [www.linkedin.com/company/HDRNRRDS](http://www.linkedin.com/company/HDRNRRDS)
    - [www.twitter.com/AmitXGarg](http://www.twitter.com/AmitXGarg)
    - [www.twitter.com/TaylorMcLinden](http://www.twitter.com/TaylorMcLinden)

  ▪ **Email:** [taylor.mclinden@ices.on.ca](mailto:taylor.mclinden@ices.on.ca) (to be added to mailing list)
1. What are pragmatic trials?

2. Example trial:

3. Example trial:

4. Example trial:

5. Pragmatic Trials Training Program